

PATENT COOPERATION TREATY



PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 03op124p	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/KR2003/002437	International filing date (day/month/year) 12 NOVEMBER 2003 (12.11.2003)	Priority date (day/month/year) 13 NOVEMBER 2002 (13.11.2002)
International Patent Classification (IPC) or national classification and IPC IPC7 A61K 9/52		
Applicant AMOREPACIFIC CORPORATION et al		

1.	This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2.	<p>This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of _____ sheets.</p>
3.	<p>This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>

Date of submission of the demand 21 MAY 2004 (21.05.2004)	Date of completion of this report 12 APRIL 2005 (12.04.2005)
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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/KR2003/002437

I. Basis of the report

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed
- ☐ the description:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the claims:
 pages _____, as originally filed
 pages _____, as amended (together with any statement) under Article 19
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the drawings:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed." and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item I and annexed to this report.

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-22	YES
	Claims		NO
Inventive step (IS)	Claims	1-22	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-22	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

The present invention of claims 1-22 is a method for preparing polymeric microparticulates comprising (1), (2), (3) steps and polymeric microparticulates obtained by the above preparation method.

1. THE PRIOR ART

The following International Search Report citations are considered in this report.

D1= US 5288502(22 February 1994)

D2= US 6264970 B1 (24 July 2001)

D1 discloses a multi-phase microspheres containing a molecular compound dispersed in a polymeric matrix.

D2 discloses a sustained release preparation comprising a bioactive substance exhibiting constantly suppressed release for an extended period of time.

2. NOVELTY

The present invention is the same as D1 in manufacturing polymeric microspheres facilitating sustained release of drug and high loading dose efficiency.

The present invention comprises the following steps: (1) preparing polymer solution; (2) preparing primary emulsion solution containing drug with said polymer solution and forming microcoagulated particles of the water-soluble polymer by dehydrating inter water phase in said primary emulsion solution, leading to encapsulation of the drug into said microparticulates; and (3) dispersing the primary emulsion solution into external continuous phase to solidify the polymeric microparticulates.

D1 is different from the present invention in manufacturing solidified microspheres with the following steps of forming multiple emulsion solvent by combining polymer on a water in oil emulsion phase of drug and surfactant, and evaporating the solvent, other than forming polymeric microparticulates by dehydration of inner water phase and encapsulating as in the present invention; and also different in that the outer continuous phase of multiple emulsion before solidification is oil phase.

(Continued on Supplemental Sheet.)

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of:

Box. V

D2 is different from the present invention in that it discloses a microcapsule formulation surrounded by polylactide group polymer, differently from the present microparticulates by forming microcoagulated particles of the water-soluble polymer.

Accordingly, the present invention is novel since it is not suggested or foreseen from the teaching of D1 and D2.

3. Inventive Step

The applicant's object is obviously to resolve the problems occurring at the time of preparing polymeric microparticulates based in multiple emulsion process, i. e. low loading amount and initial burst of drug. And another object lies in providing polymeric microparticulates enabling sustained release of drug and their preparation method.

In table 1 they show the high loading amount and loading efficiency of active drug and in experimental example 2, the drug encapsulated by both water-soluble polymer and polyester polymer appears to be inhibited in its initial burst and be controlled in its release continuously for a long period of time.

The prior art cited in the international search report does not teach or suggest the present method and microparticulates therefrom.

Accordingly, claims 1-22 of the present invention are inventive since they cannot be easily derived by a person skilled in the art from the prior art.

4. Industrial Applicability

The subject matter of claims 1-22 is considered to be industrially applicable under PCT Article 33(4).